KANSAS

KATHLEEN SEBELIUS, GOVERNOR

DEPARTMENT OF AGRICULTURE
ADRIAN J. POLANSKY, SECRETARY

January 21, 2005

Docket No. 2004D-0369
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20852

RE: Docket 2004D-0369

Ladies and Gentlemen:

I recently met with a diverse group of stakeholders to review and discuss the above-referenced docket. It has been our practice to provide comments on items where consensus among our group is achieved.

We applaud FDA for providing the document titled "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."

These nonbinding guidelines provide industry an opportunity to interact with FDA early in the process of developing new proteins to minimize the risk of developing proteins that may be an allergen or a toxin. We believe this opportunity for early, voluntary communication between industry and FDA is good.

An early review is advantageous for both FDA and industry. It will allow industry to maximize the use of its resources in developing new products. Early reviews also will provide FDA an opportunity to evaluate potential new proteins for allergenicity and toxicity potential.

With regard to the guidelines document itself, we encourage FDA to clarify the language on page 7, item C1 with regard to field testing. Does this language mean that FDA is recommending that the submitter identify potential pathways for the protein to enter the food supply and to make those pathways known to FDA prior to field testing?

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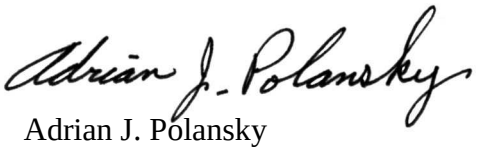
With regard to the reporting burden estimates, the only question we have is that, since this is a new effort, will FDA be able to commit sufficient resources to performing these early food safety reviews without having to redirect resources from other tasks? Based on our analysis of the data provided in the docket, it appears industry's reporting burden is not excessive. However, the docket does not indicate whether FDA will need to dedicate any additional resources to performing these early reviews.

Although not mentioned in your Federal Register notice, I continue to believe that federal agencies with a hand in biotechnology regulation – EPA, USDA and FDA – should improve their communication about which agencies regulate what and when. When I meet with stakeholders, we always come back to the regulatory framework and how it functions because it's not always clear to us. Perhaps an easy-to-follow flow chart would be the most effective way to communicate about your regulatory roles.

Thank you for the opportunity to comment. Please feel free to contact us if you have questions or need additional information.

Sincerely,



Adrian J. Polansky
Secretary of Agriculture

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